

## Patent claims

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1. A kit for directly detecting a RS virus related biological cell present in a sample in an amount of less than about 2000 per microlitre ( $10^{-6}$  litre), said kit comprising
- a solid support, and
  - a plurality of a first targeting species bound to the solid support, said targeting species being capable of directly detecting said predetermined RS virus related biological cell when it is present in a sample that is brought into contact with the solid support, and
  - a conjugate comprising a polymeric carrier molecule bound to
  - at least one first and/or second targeting species capable of directly detecting said predetermined RS virus related biological cell when it is present in a sample that is brought into contact with the solid support, and
  - at least one labelling species.

2. Kit according to claim 1, wherein the conjugate comprises

- a polymeric carrier molecule comprising a plurality of at least one reactive, functional group,
- at least one connecting moiety attached to the at least one reactive, functional group,
- at least one molecular species selected from the group of molecular species consisting of targeting species and labelling species, wherein each of the molecular species comprises at least one functional group that is reactive with at least one connecting moiety attached to the reagent,
- wherein the conjugate comprises at least one molecular species covalently attached thereto via a connecting moiety.

3. Kit according to claim 2, wherein the polymeric carrier molecule comprises reactive, functional groups in an amount of from about 5 to about 5,000  $\mu$ moles per gram of polymeric carrier.

4. Kit according to any of the preceding claims, wherein the RS virus related biological cell capable of being directly detected by a targeting species is a virus particle.

5. Kit according to claim 4, wherein the virus capable of being directly detected by a targeting species belongs to the genus paramyxoviridae.

6. Kit according to claim 5, wherein the virus is respiratory syncytial virus.

7. Kit according to any of the preceding claims, wherein the targeting species is selected from the group of species consisting of antigens; haptens; monoclonal and polyclonal antibodies; gene probes; natural and synthetic oligo- and polynucleotides; natural and synthetic mono-, oligo- and polysaccharides; lectins; avidin and streptavidin; biotin; growth factors; hormones; receptor molecules; protein A; and protein G.

8. Kit according to claim 7, wherein the targetting species is selected from monoclonal and polyclonal antibodies.

9. Kit according to claim 8, wherein the targetting species is an antibody recognising a nucleoprotein of RS virus or a glycoprotein of RS virus.

10. Kit according to any of the preceding claims, wherein the labelling species is selected from the group of species consisting of proteins; enzymes; toxins; drugs; dyes; fluorescent, luminescent, phosphorescent and other light-emitting substances cells; metal-chelating substances; substances labelled with a radioactive isotope; and substances labelled with a heavy atom.

11. Kit according to any of claims 1 and 2, wherein the labelling species is selected from the group of species consisting of ferritin, phycoerythrins, phycocyanins, phycobilins, horseradish peroxidase, alkaline phosphatase, glucose oxidases, galactosidases, ureases, iminodiacetic acid, ethylenediaminetetraacetic acid, diethylenetriaminepentaacetic acid, and desferrioxamine B.

12. Kit according to any of claims 1 and 2, wherein the first and second targeting species are identical.

13. Kit according to any of claims 1 and 2, wherein the first and second targeting species are non-identical.

14. Kit according to any of claims 1 and 2, wherein the polymeric carrier is selected from the group of polymers consisting of natural and synthetic polysaccharides; homopoly amino acids; natural and synthetic polypeptides and proteins; and synthetic polymers having nucleophilic functional groups.

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15. Kit according to any of claims 1 and 2, wherein the polymeric carrier is selected from the group of polymers consisting of polyvinyl alcohols, polyallyl alcohols, polyethylene glycols and substituted polyacrylates.

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16. Kit according to any of claims 1 and 2, wherein the polymeric carrier is selected from the group consisting of dextrans, carboxymethyl-dextrans, starches, hydroxyethyl-starches, hydroxypropyl-starches, glycogen, agarose derivatives, cellulose derivatives and natural gums.

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17. Kit according to claim 11, wherein the polymeric carrier is a dextran.

18. Kit according to any of claims 1 and 2, wherein the polymeric carrier is selected from the group consisting of hydroxyethyl-celluloses and hydroxypropyl-celluloses.

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19. Kit according to any of the preceding claims, said kit being a dip-stick.

20. Kit according to any of the preceding claims, said kit being adapted for a microsystem.

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21. Kit according to any of claims 1 to 20, further comprising means for detecting at least one inflammatory indicator.

22. Kit according to claim 21, wherein the at least one inflammatory indicator is a cytokine.

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23. Kit according to claim 22, comprising means for detecting at least 3 different cytokines.

24. Method of detecting a RS virus related predetermined RS virus related biological cell present in a sample, said method comprising the steps of

- i) contacting the sample with the kit of any of claims 1 to 24, and
- ii) detecting a targeting species capable of targeting the predetermined RS virus related biological cell,

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wherein the detection of the targeting species is indicative of the presence of the RS virus-related biological cell in the sample.

25. Method according to claim 24, wherein the sample is a body fluid sample.

26. Method according to claim 24 or 25, said kit further comprising means for detecting at least one predetermined inflammatory indicator, said method comprising the steps of

i) contacting the sample with a kit comprising

a) a solid support, and

b) a plurality of a first targeting species bound to the solid support, said targeting species being capable of directly detecting said predetermined RS virus related biological cell when it is present in a sample that is brought into contact with the solid support, and

c) a conjugate comprising a polymeric carrier molecule bound to i) at least one first and/or second targeting species capable of directly detecting said predetermined RS virus related biological cell when it is present in a sample that is brought into contact with the solid support, and ii) at least one labeling species,

and

ii) detecting a targeting species capable of targeting the predetermined inflammatory indicator,

wherein the detection of the targeting species is indicative of the presence of the predetermined inflammatory indicator in the sample.

27. Method according to claim 26, wherein the inflammatory indicator is present in the sample in an amount of less than about 100 nanograms ( $100 \times 10^{-9}$  grams) per millilitre ( $10^{-3}$  litre).

28. Method according to any of claims 24-27, wherein the polymeric carrier molecule comprises i) a plurality of at least one reactive, functional group, ii) at least one connecting moiety attached to the at least one reactive, functional group, and iii) at least one molecular species selected from the group of molecular species consisting of targeting spe-

cies and labelling species, wherein each of the molecular species comprises at least one functional group that is reactive with at least one connecting moiety attached to the reagent, and wherein the conjugate comprises at least one molecular species covalently attached thereto via a connecting moiety.

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29. Method according to any of claims 24-28, wherein the targeting species is selected from the group of species consisting of antigens; haptens; monoclonal and polyclonal antibodies; gene probes; natural and synthetic oligo- and polynucleotides; natural and synthetic mono-, oligo- and polysaccharides; lectins; avidin and streptavidin; biotin; growth factors; hormones; receptor molecules; protein A; and protein G.

30. Method according to any of claims 24-29, wherein the labelling species is selected from the group of species consisting of proteins; enzymes; toxins; drugs; dyes; fluorescent, luminescent, phosphorescent and other light-emitting substances; metal-chelating substances; substances labelled with a radioactive isotope; and substances labelled with a heavy atom.

31. Method according to any of claims 24-30, wherein the labelling species is selected from the group of species consisting of ferritin, phycoerythrins, phycocyanins, phycobilins, horseradish peroxidase, alkaline phosphatase, glucose oxidases, galactosidases, ureases, iminodiacetic acid, ethylenediaminetetraacetic acid, diethylenetriaminepentaacetic acid, and desferrioxamine B.

32. Method according to any of claims 24-31, wherein the polymeric carrier is selected from the group of polymers consisting of natural and synthetic polysaccharides; homopoly amino acids; natural and synthetic polypeptides and proteins; and synthetic polymers having nucleophilic functional groups.

33. Method according to any of claims 24-32, wherein the polymeric carrier is selected from the group of polymers consisting of polyvinyl alcohols, polyallyl alcohols, polyethylene glycols and substituted polyacrylates.

34. Method according to any of claims 24-33, wherein the polymeric carrier is selected from the group consisting of dextrans, carboxymethyl-dextrans, starches, hydroxyethyl-starches, hydroxypropyl-starches, glycogen, agarose derivatives, cellulose derivatives and natural gums.

35. Method according to claim 34, wherein the polymeric carrier is a dextran.

36. Method according to any of claims 24-34, wherein the polymeric carrier is selected from the group consisting of hydroxyethyl-celluloses and hydroxypropyl-celluloses.

37. Method according to any of claims 24 to 36, wherein the predetermined inflammatory indicator is selected from the group consisting of agonists from the IL-1 system, preferably IL-1 $\alpha$ , IL-1 $\beta$ , IL-1ra, autoantibodies against IL-1 $\alpha$ , sIL1-RI and sIL1-RII.

38. Method according to any of claims 24 to 37, wherein the predetermined inflammatory indicator is selected from the group consisting of agonists from the TNF $\alpha$  system, preferably sTNFR p55 and p75.

39. Method according to any of claims 24 to 38, wherein the predetermined inflammatory indicator is selected from the group consisting of IL-6 and autoantibodies against IL-6.

40. Method according to any of claims 24 to 39, wherein the predetermined inflammatory indicator is selected from the group consisting of IL-12, sIL-4R, TNF $\beta$  (LT), INF $\gamma$ , IL-4, and IL-10.

41. Method according to any of claims 24 to 40, wherein the predetermined inflammatory indicator is selected from the group consisting of IL-2, RANTES, IL-8, sIL-2R, IL-18, IFN $\alpha$ , and eosinophil cationic protein.

42. A method for diagnosing a RS virus infectious condition in an individual, said method comprising the steps of

- iii) detecting a predetermined RS virus related biological cell present in a body fluid sample according to any of claims 24 to 41, and
- iv) diagnosing said infectious condition.

43. A method for diagnosing a RS virus infectious condition in an individual, said method comprising the steps of

- iv) detecting a predetermined RS virus related biological cell present in a body fluid sample according to any of claims 24 to 42,
- v) detecting a predetermined inflammatory indicator present in a body fluid sample according to any of claims 26 to 42, and

~~vi) diagnosing said infectious condition.~~

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iii) performing a diagnosis according to any of the methods of claim 43, and

- iv) treating the infectious condition based on the diagnosis.